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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/501,102	02/09/2000	Man Sung Co	WYS-00401	3404

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EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 11/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/501,102	CO ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *143-160* is/are pending in the application.

4a) Of the above claim(s) *143-144, 148 and 155-160* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *145-147 and 149-154* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 8/14/06, has been entered.
Claims 145-147 and 154 have been amended.

Claims 145-147 and 149-154, as they read on the elected invention, including the elected species of the combination of anti-B7-1 antibodies, anti-B7-2 antibodies and cyclosporin or rapamycin in the claimed methods are under consideration in the instant application.

Claims 143-144, 148 and 155-160 have been withdrawn from further consideration by the examiner, 37 C.F.R. 1 § 1.142(b) as being drawn to a nonelected inventions and species.

Claims 1-142 have been canceled previously.

2. The filing date of the instant claims is deemed as follows.

While It appears that priority USSN 09/249,011, now U.S Patent No. 6,972,125 provides for the recitation of "α CD40 ligands" as another drug that can be administered with B7-1- / B7-2-specific antibodies" (e.g., see column 18, paragraph 2 of U.S. Patent No. 6,972,125),
this priority document does not provide sufficient written description of the newly amended claim limitation "wherein an inhibitor of CD40 or CD40 ligand is not administered to the transplant recipient", as broadly claimed in the instant claims.

While It appears that priority USSN 09/339,596, now U.S Patent No. 6,913,747 provides for the recitation of "anti-CD40 ligands" as another drug that can be administered with B7-1- / B7-2-specific antibodies" (e.g., see column 24, paragraph 5 of U.S. Patent No. 6,913,747);
this priority document does not provide sufficient written description of the newly amended claim limitation "wherein an inhibitor of CD40 or CD40 ligand is not administered to the transplant recipient", as broadly claimed in the instant claims.

While It appears that the instant USSN 09/501,102 provides for the recitation of "anti-CD40 pathway inhibitors (e.g. anti-CD40 antibodies, anti-CD40 ligand antibodies and small molecule inhibitors of the CD40 pathway" as another drug that can be administered with B7-1- / B7-2-specific antibodies" (e.g., see page 42, paragraph 2 of the instant specification);
the instant application does not provide sufficient written description of the newly amended claim limitation "wherein an inhibitor of CD40 or CD40 ligand is not administered to the transplant recipient", as broadly claimed in the instant claims.

The instant claims now recite limitations which were not clearly disclosed in the priority applications as well as the specification as-filed, and would have changed the scope of the priority applications and do change the scope of the instant disclosure as-filed.

Further, neither the priority applications nor the instant application have provides a sufficient description of a representative number of species of "inhibitors of CD40 or CD40 ligand" to represent the entire genus of "inhibitors of CD40 or CD40 ligand", broadly encompassed by the current claims.

For example, it cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See In re Smith 173 USPQ 679, 683 (CCPA 1972). Also see MPEP 2163.05.

Therefore, reliance upon the genus of "drugs" and the disclosure of certain "inhibitors of CD40 or CD40 ligand" (e.g. anti-CD40 antibodies, anti-CD40 ligand antibodies) does not provide sufficient written description for certain "inhibitors of CD40 or CD40 ligand", as currently claimed.

Further, there does not appear to be sufficient description showing possession of the necessary functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genera of "α CD40 ligands" "anti-CD40 ligands" and "small molecule inhibitors of the CD40 pathway" consistent with written description provisions of 35 USC 112, first paragraph, and the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, § 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday January 2001.

Therefore, there appears to be insufficient written description for the phrase "wherein an inhibitor of CD40 or CD40 ligand is not administered to the transplant recipient", as broadly claimed in the instant claims in the priority documents as well as in the instant specification.

Therefore, given the lack of written description of the claimed methods as indicated herein and below, the instant claims do not appear to have the priority date of USSNs 09/339,596 and 09/249,011.

If applicant desires priority back to their priority documents,
applicant is invited to point out and provide documentary support for the priority of the instant claims.

Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. § 112, first paragraph.

A claim as a whole has only one effective filing date.
See Studiengelsellschaft Kahle m.b.H. v. Shell Oil Co. 42 USPQ2d 1674, 1677 (Fed. Cir 1997).

3. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Upon reconsideration of applicant's amended claims, filed 8/14/06; the previous rejection under 35 U.S.C. § 112, first paragraph, written description / new matter with respect to the recitation of "at least one" has been withdrawn.

5. Claims 145-147 and 149-154 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed.
The specification as originally filed does not provide support for the invention as now claimed:
"wherein an inhibitor of CD40 or CD40 ligand is not administered to the transplant recipient".

Applicant's amendment, filed 8/14/0610/02/02, simply asserts that no new matter has been added and does not provide any direction to the written support of the newly added claim either in the instant application or in the priority applications.

The recitation of "wherein an inhibitor of CD40 or CD40 ligand is not administered to the transplant recipient" is not readily apparent either in the pending or in the earlier priority applications.

While It appears that priority USSN 09/249,011, now U.S Patent No. 6,972,125 provides for the recitation of "α CD40 ligands" as another drug that can be administered with B7-1- / B7-2-specific antibodies" (e.g., see column 18, paragraph 2 of U.S. Patent No. 6,972,125),
this priority document does not provide sufficient written description of the newly amended claim limitation "wherein an inhibitor of CD40 or CD40 ligand is not administered to the transplant recipient", as broadly claimed in the instant claims.

While It appears that priority USSN 09/339,596, now U.S Patent No. 6,913,747 provides for the recitation of "anti-CD40 ligands" as another drug that can be administered with B7-1- / B7-2-specific antibodies" (e.g., see column 24, paragraph 5 of U.S. Patent No. 6,913,747);

this priority document does not provide sufficient written description of the newly amended claim limitation "wherein an inhibitor of CD40 or CD40 ligand is not administered to the transplant recipient", as broadly claimed in the instant claims.

While It appears that the instant USSN 09/501,102 provides for the recitation of "anti-CD40 pathway inhibitors (e.g. anti-CD40 antibodies, anti-CD40 ligand antibodies and small molecule inhibitors of the CD40 pathway" as another drug that can be administered with B7-1- / B7-2-specific antibodies" (e.g., see page 42, paragraph 2 of the instant specification);
the instant application does not provide sufficient written description of the newly amended claim limitation "wherein an inhibitor of CD40 or CD40 ligand is not administered to the transplant recipient", as broadly claimed in the instant claims.

The instant claims now recite limitations which were not clearly disclosed in the priority applications as well as the specification as-filed, and would have changed the scope of the priority applications and do change the scope of the instant disclosure as-filed.

Further, neither the priority applications nor the instant application have provides a sufficient description of a representative number of species of "inhibitors of CD40 or CD40 ligand" to represent the entire genus of "inhibitors of CD40 or CD40 ligand", broadly encompassed by the current claims.

For example, it cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See In re Smith 173 USPQ 679, 683 (CCPA 1972). Also see MPEP 2163.05.

Therefore, reliance upon the genus of "drugs" and the disclosure of certain "inhibitors of CD40 or CD40 ligand" (e.g. anti-CD40 antibodies, anti-CD40 ligand antibodies) does not provide sufficient written description for certain "inhibitors of CD40 or CD40 ligand", as currently claimed.

Further, there does not appear to be sufficient description showing possession of the necessary functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genera of "α CD40 ligands" "anti-CD40 ligands" and "small molecule inhibitors of the CD40 pathway" consistent with written description provisions of 35 USC 112, first paragraph, and the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, § 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday January 2001.

Given the lack of sufficient description showing possession of the necessary functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genera of "α CD40 ligands" "anti-CD40 ligands" and "small molecule inhibitors of the CD40 pathway",

applicant's newly added limitation of reciting a negative limitation based upon the limited disclosure in the instant and priority applications raise new matter under 35 USC 112, first paragraph, written description.

Therefore, there appears to be insufficient written description for the phrase "wherein an inhibitor of CD40 or CD40 ligand is not administered to the transplant recipient", as broadly claimed in the instant claims in the priority documents as well as in the instant specification.

The specification as filed does not provide a sufficient written description or set forth the metes and bounds of this phrase. The specification does not provide blazemarks nor direction for the instant methods encompassing the above-mentioned "limitation", as currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office Action.

Alternatively, applicant is invited to provide sufficient written support for the "limitation" indicated above.

See MPEP 714.02 and 2163.06

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the

United States and was published under Article 21(2) of such treaty in the English language.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

8. Since the priority date of the instant claims may be in question the following rejection are made under 35 U.S.C. § 102 (b)(e), as it would apply to the priority of the instant claims.

9. Upon reconsideration of applicant's amended claims, filed 8/14/06, which now recite "wherein an inhibitor of CD40 or CD40 ligand is not administered to the transplant recipient", the previous rejection under 35 U.S.C § 102(b)(e) has been withdrawn.

10. Claims 145-147 and 154 are rejected under 35 U.S.C § 102(e) as being anticipated by Freeman et al. (U.S. Patent No. 6,605,279) (see entire document).

Freeman et al. teach methods of downregulating or suppressing T cell mediated immune responses, including the use of B7-1-specific and B7-2-specific antibodies in conjunction with other immunomodulating reagents such as cyclosporine or FK506, including it usefulness in situations of tissue and organ transplantation as well as GVHD (see entire document, particularly Other Therapeutic Reagents on columns 32-34).

It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure

11. Claims 145-147 and 149-154 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman et al. (U.S. Patent No. 6,605,279) in view of the well known use of immunosuppressives such as cyclosporin, FK506 and rapamycin and effective therapeutic antibody dosages in transplantation therapeutic regimens at the time the invention was made, as taught by de Boer et al. (U.S. Patent No. 5,757,034) (1449).

Freeman et al. teach methods of downregulating or suppressing T cell mediated immune responses, including the use of B7-1-specific and B7-2-specific antibodies in conjunction with other immunomodulating reagents such as cyclosporine or FK506, including it usefulness in situations of tissue and organ transplantation as well as GVHD (see entire document, particularly Other Therapeutic Reagents on columns 32-34).

While Freeman et al. teach the administration of therapeutically effective amounts of the therapeutic compositions, wherein amounts of effective dosages are administered for periods of time necessary to achieve the desired results (e.g. see Administration of Therapeutic Forms of B Lymphocytes Antigens on columns 37-39), Freeman et al. differs from the claimed methods by not disclosing the well known use of immunosuppressives such as rapamycin and effective therapeutic antibody dosages in transplantation therapeutic regimens at the time the invention was made .

De Boer et al. teach the use of B7-specific antibodies in combination with immunosuppressive agents such as cyclosporin, FK506 and rapamycin (e.g., see column 14, paragraphs 2-3) in therapeutic amounts and modes of administration encompassed by the claimed invention (e.g., see column 16, paragraph 5) (see entire document).

One of ordinary skill in the art at the time the invention was made would have been motivated to modify the teachings of Freeman et al. to incorporate the well known use of immunosuppressives such as as cyclosporin, FK506 and rapamycin and effective therapeutic antibody dosages in transplantation therapeutic regimens at the time the invention was made to achieve the desired therapeutic result of inhibiting graft rejection and promoting long term graft survival with effective amounts of standard immunosuppressives and effective amounts of therapeutic antibodies. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

12. No claim allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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October 24, 2006